JUN 17 2010

Section 5

Revised 510(k) Summary

K100425

510(K) SUMMARY

Haskal™ Torque Device
510(k) Number K100425

1. Applicant's Name:

Elcam Medical ACAL.

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2. Contact Person:

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3. Trade Name:

Haskal™ Torque Device

4. Classification:

Name:	Guide wire torquer
Product Code:	DQX
Regulation No:	870.1330
Class:	II
Classification Panel:	Cardiovascular

5. Predicate Devices:

- Guide Wire Torque Device (Merit Medical), catheter guide wire, product code DQX, cleared for marketing under K072552
- WireClip™ Torquer (Boston Scientific Corporation), guide wire torquer, product code DQX, cleared for marketing under K003398

6. Intended Use:

The Haskal™ Torque Device is intended to facilitate steering of guidewires during interventional procedures.

7. Device Description:

The Haskal™ Torque Device is a one-piece molded unit with rows of interlocking "teeth". When the sides of the device are squeezed, the "teeth" line up and a groove is exposed in the center. The device is then positioned with the guidewire in the groove. When the sides are released, the device "teeth" close onto the guidewire to secure it firmly. The Haskal™ accommodates guidewires with diameters between 0.010 inches to 0.038 inches.

The Haskal™ is designed to be mounted onto the guidewire from the side with one hand, eliminating the need for threading along the wire starting from the distal end. It can also be released from the guide wire or repositioned as the guide wire advances by squeezing it on both sides to release the wire.

The Haskal™ is a sterile, non-pyrogenic single use device. It is manufactured in several colors.

8. Technological Characteristics:

The Haskal™ technological characteristics are the same as those of its predicate devices. It is an accessory torque device for attaching to guidewires, is compatible for use with guidewires of varying types, diameters and lengths, and can be positioned and repositioned on the guidewire. Same as the predicates, rotating the device results in steering of the guidewire.

Identical to the predicates, Haskal™ is a sterile, non-pyrogenic single use device manufactured from biocompatible materials and sterilized by ETO.

Identical to the WireClip predicate, Haskal™ is a one-piece **side-mounted vise grip device**, loaded by squeezing with 2 fingers to create a groove in the device into which the guidewire is placed. Release of the squeeze action allows the groove to close around the guidewire securing and firmly gripping it.

9. Summary of Supporting Data:

The Haskal™ Torque Device performance characteristics were evaluated in the following in-vitro/bench studies:

- Packaging Environmental Endurance
- Dimensions Verification
- Device and Guidewire Axial Force
- Torque Force
- Device Operational Force
- Performance During Exposure to Fluids
- Usability
- Sterility Integrity and Shelf life

- Biocompatibility:
  - Cytotoxicity
  - Systemic toxicity
  - Sensitization
  - Irritation
  - Subchronic toxicity
  - Genotoxicity
  - Haemocompatibility- Hemolysis
    The torquer device remains outside the patient's body during the medical procedures and there is no contact with the blood. Therefore the Hemolysis test we perform is additional for the requirement of this device.

Results of nonclinical testing demonstrated that the device is as safe, as effective, and performs as well as the legally marketed devices identified in paragraph 5 of this section.

10. Conclusion:

Elcam Medical believes that, based on the information provided in this submission, the Haskal™ Torque Device is substantially equivalent to its predicate devices without raising any new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 17 2010

Elcam Medical, Inc.
c/o Mr. Lloyd Fishman
President
2 University Plaza, Suite 620
Hackensack, NJ 07601

Re: K100425
Trade/Device Name: Haskal™ Torque Device
Common Name: Wire, Guide, Catheter
Regulation Number: 21 CFR 870.1330
Regulatory Class: II
Product Code: DQX
Dated: June 6, 2010
Received: June 10, 2010

Dear Mr. Fishman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Donna R. Zuckerman

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K100425

Device Name:

Haskal™ Torque Device

Indications for Use:

The Haskal™ Torque Device is intended to facilitate steering of guidewires during interventional procedures.

Prescription Use ___X___ OR Over the Counter Use_____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

510(k) Number K100425

Donna R. Kaufman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100425